

# **Research Planning for Cumulative Risk Assessment**

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**Office of Research and Development (ORD)**

**National Center for Environmental Assessment - Cincinnati, Ohio**

**ORD/Regional Cumulative Risk Assessment Workshop**

**Dallas, TX**

**November 4-8, 2002**

## **Research Planning Goals for Cumulative Risk Workshop**

- (1) Identify program office and regional needs;**
- (2) Identify available tools and methods for conducting cumulative risk assessments;**
- (3) Address special cumulative risk issues;**
- (4) Discuss approaches, tools and experiences related to cumulative risk**
- (5) Collect information to identify future research needs and directions for conducting cumulative risk assessments.**

# **Format for the Research Planning Aspect of Workshop**

## **Monday - This talk!!**

Introduce Research Planning Processes

Explain Format and Objectives for Workshop

## **Tuesday-Thursday**

Co-Chairs Introduce Major Theme Areas in the Morning

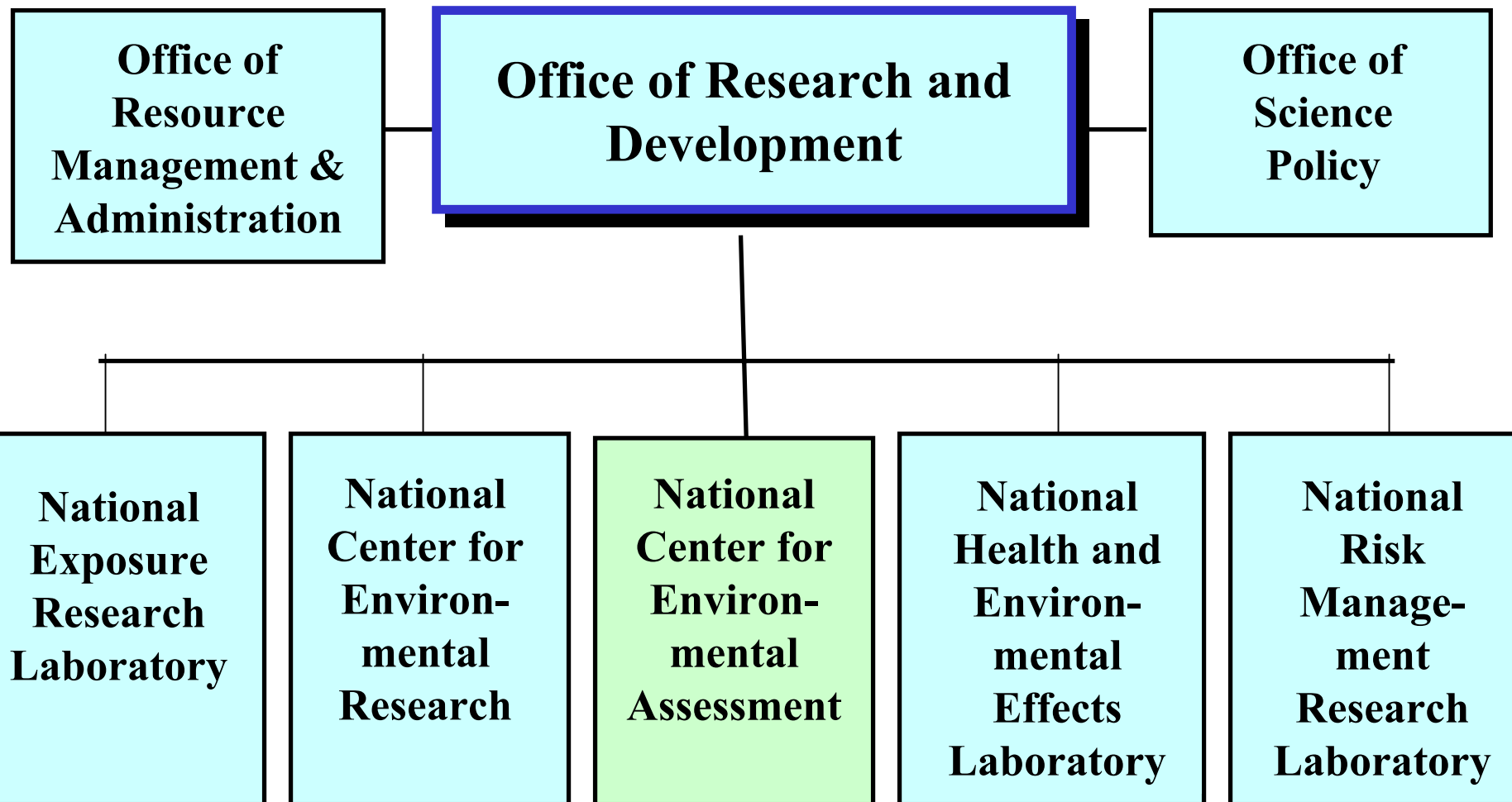
Four Breakout Groups Each Day

- Discuss Research Themes
- Develop Research ideas
- Prioritize
- Report Out to Larger Group

## **Friday**

Summary of Ideas Generated During the Workshop

# Who Will Use the Results of our Research Planning Efforts?



# ORD's National Center for Environmental Assessment Organization Chart

***George Alapas, Acting Director, Washington, D.C.***

Associate  
Director for  
**Health**  
*Herman Gibb*

Associate  
Director for  
**Ecology**  
*Michael W. Slimak*

Acting Deputy  
Director for  
**Management**  
*Art Payne*

**National  
Center for  
Environmental  
Assessment**

**RTP Office**

*Lester D. Grant, Ph.D.*

**National  
Center for  
Environmental  
Assessment**

**Washington, D.C. Office**

*Dave Bussard, Acting*

**National  
Center for  
Environmental  
Assessment**

**Cincinnati Office**

*Steve Lutkenhoff,  
Acting*

# **ORD's National Center for Environmental Assessment Primary Functions**

**The National Center for Environmental Assessment (NCEA) has three primary functions:**

- 1. To complete risk assessments or develop descriptions of risk information for EPA program offices and the public**
- 2. To develop Agency guidance and tools on how to do risk assessments**
- 3. To promote research to carry out new risk assessment technology and applications**

**Leadership  
Team**

**National Center for Environmental  
Assessment – Cincinnati Division**

**Manage-  
ment  
Team**

**Risk  
Assessment  
Support  
Team**

**Public  
Health &  
Microbial  
Risk  
Assessment  
Team**

**Cumulative  
Risk  
Assessment  
Team**

**Ecological  
Risk  
Assessment  
Team**

**Informa-  
tion  
Manage-  
ment  
Team**

**Eletha Brady-Roberts   Rick Hertzberg**  
**John Lipscomb   Linda Teuschler   Doug Williams**

# NCEA-Cin Cumulative Risk Assessment Team Objectives

## SHORT-TERM OBJECTIVES

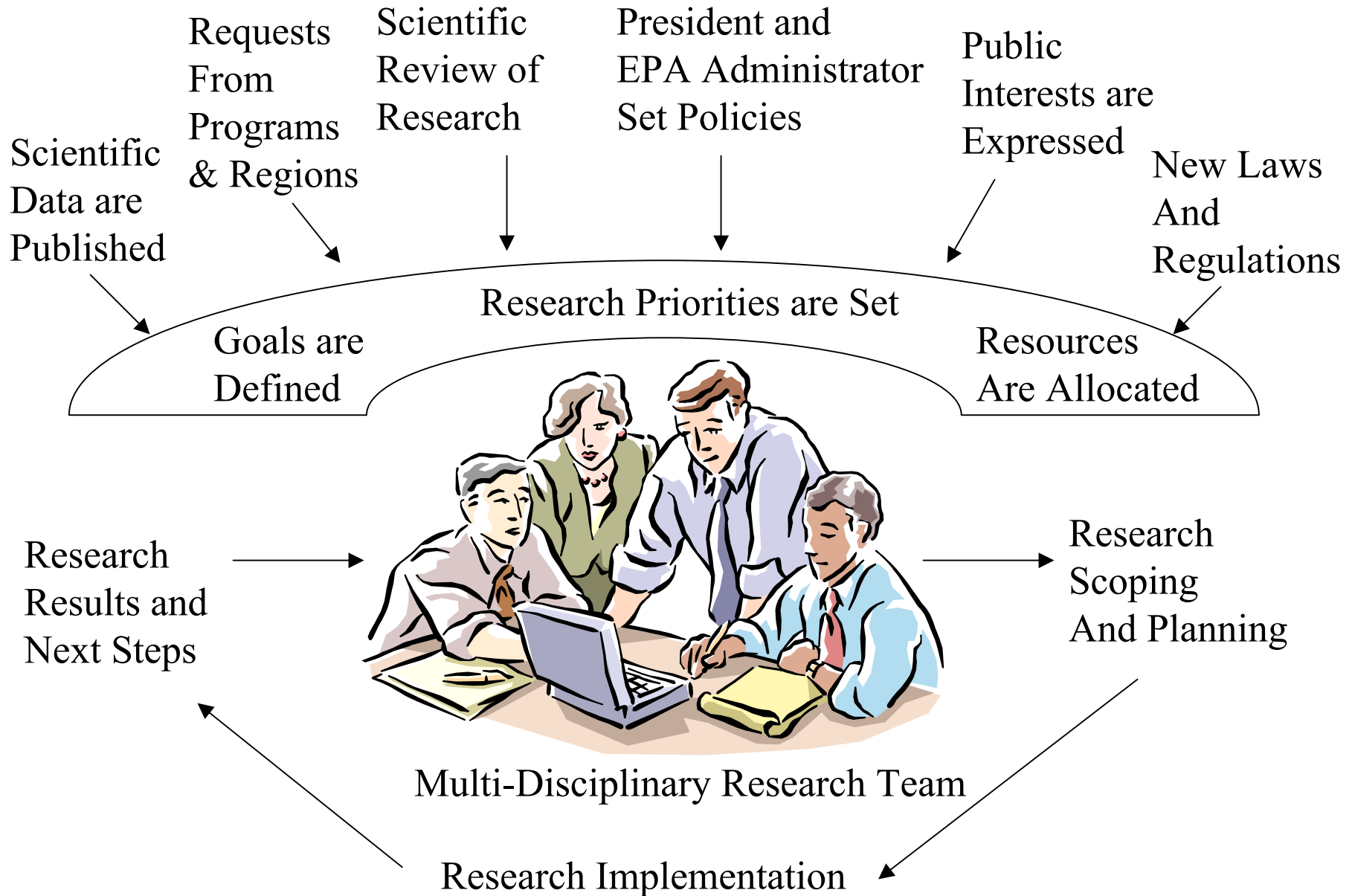
- *Identify Program and Regional Office needs and priorities related to aggregate exposure and cumulative risks.*
- Develop examples of multiple pathway approaches to aggregate exposures and cumulative risks using selected stressors.
- Develop examples of cumulative risk assessment by integrating multiple pathway approaches with mixtures risk guidance methods.

## LONG-TERM GOALS

- Develop innovative methods, models, and guidance for assessing aggregate exposures and cumulative risks within a 5-year time frame.
- *Develop state-of-the-art cumulative risk assessment capabilities and apply these skills in the form of guidance to Risk Managers, Program and Regional Offices, and the scientific global community.*



# Influences on ORD Research Planning Processes



# Cumulative Risk Assessment Research in the Law

## Food Quality Protection Act (1996)

Consider potential human health *risks from all pathways of dietary and nondietary exposures to more than one pesticide* acting through a common mechanism of toxicity.

## Safe Drinking Water Act Amendments (1996)

Develop new approaches to the *study of complex mixtures*, such as mixtures found in drinking water

## CERCLA (1980)

‘...Contaminant’ shall include, but not be limited to, any element, substance, compound, or *mixture.....* which after release into the environment.....may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer..... in such organisms or their offspring.

# **Public Input to Research Planning**

**Expert Panel Scientific Reviews**

**National Research Council**

*Science and Judgment in Risk Assessment (1994)*

**Science Advisory Board**

**Public Interest Groups**

**Stakeholder Meetings**

**Federal State and Territorial Research Advisory Committees**

**Professional Scientific Societies**

# ORD Strategic Plan

## Cumulative Risk Research Incorporated

### EPA Strategic Goal 2: Clean and Safe Water

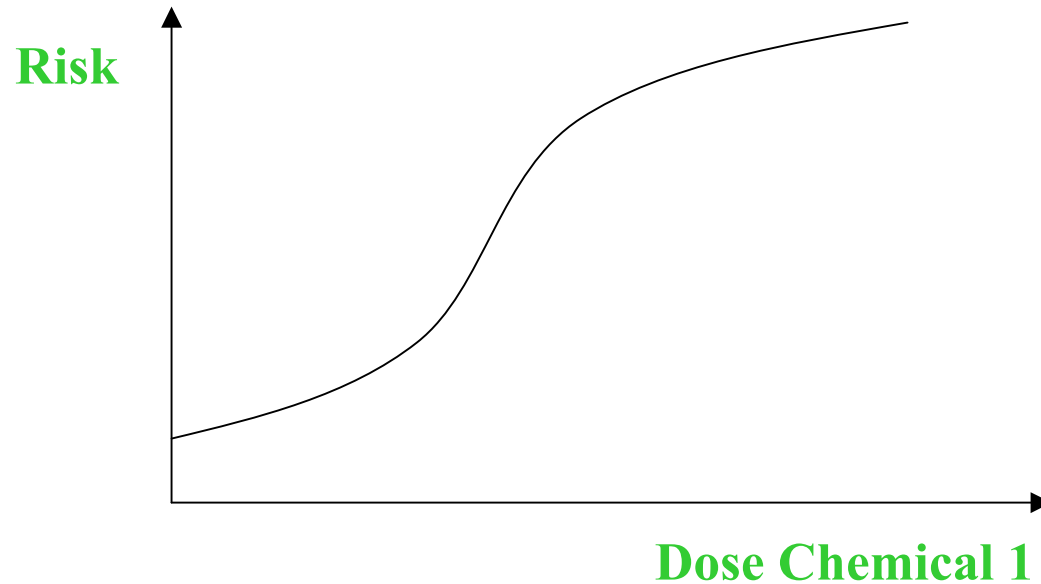
Use population dynamic models to estimate the *cumulative risks* of critical habitat disturbance and contaminated sediments on the integrity of fish, shellfish, and other communities.

### EPA Strategic Goal 8: Sound Science

Identify the *interactive effects from exposures to chemical mixtures* with common or different modes of action.

Develop improved models and methodologies to better *estimate human exposures, assess aggregate exposures to single stressors, and assess cumulative risks from exposures to multiple stressors.*

# Single Chemical *Risk Characterization*

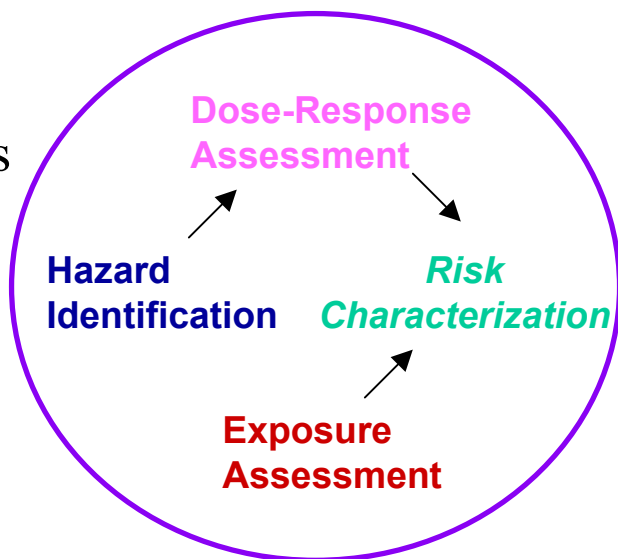


- Single Chemical
- One Exposure Route
- Single Critical Effect
- Specific Duration

# Risk Assessment Paradigm for Single Chemicals

## *Hazard identification:*

- identify health effects from exposure to the chemical
- consider severity of the effects



## *Dose-response:*

- find relationship between dose and effect
- incorporate judgments regarding applicability of dose-response to humans

## *Exposure assessment:*

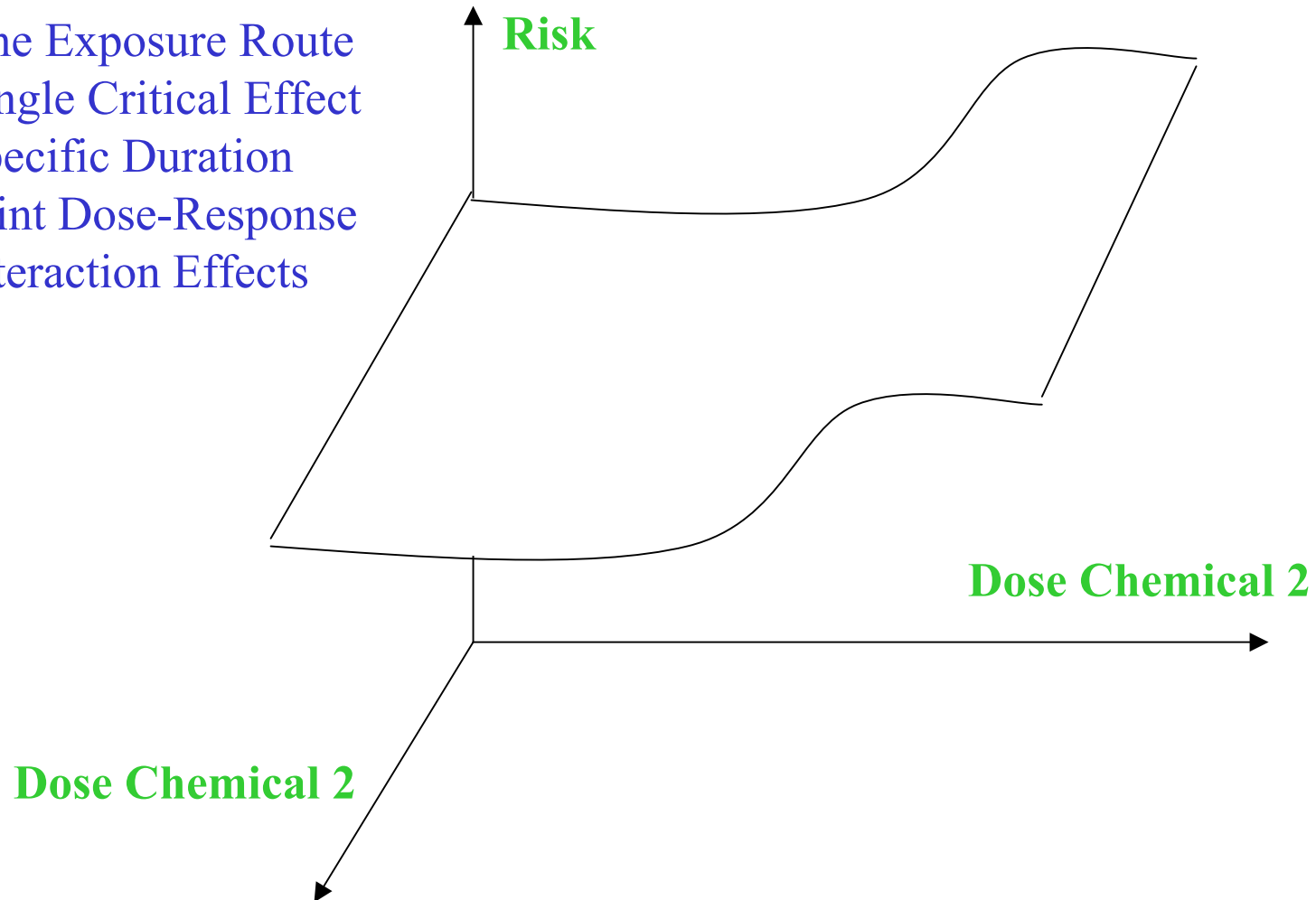
- measure the chemical in environmental media
- account for human consumption or contact with the media

## *Risk characterization:*

- describe uncertainty and variability in the risk assessment, including data gaps, model uncertainty
- clearly state assumptions made

# Mixtures *Risk Characterization*

- Several Chemicals
- One Exposure Route
- Single Critical Effect
- Specific Duration
- Joint Dose-Response
- Interaction Effects



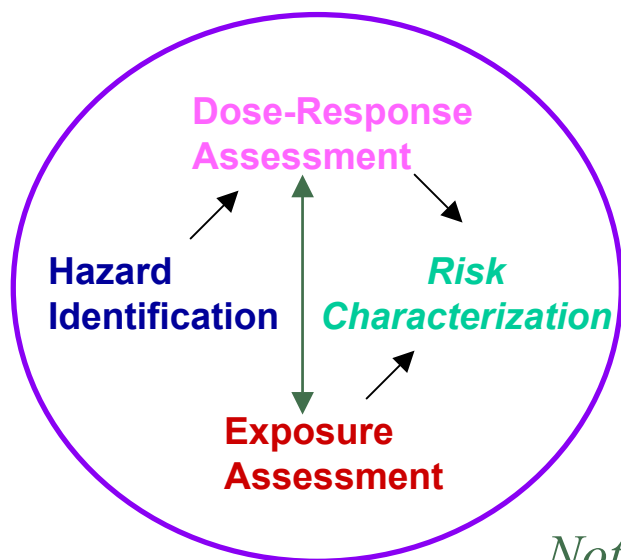
# Risk Assessment Paradigm for Mixtures: In Addition to Issues for Single Chemicals

## *Hazard identification:*

- consider potential interaction effects
- identify effects from total mixture dose.

## *Exposure assessment:*

- account for chemical characterization of unidentified material
- evaluate degradation of the mixture in the environment.



## *Dose-response:*

- consider potential for effects below individual chemical thresholds
- incorporate toxicologic judgment of similar toxicity within or between mixtures.

*Note: Dose-response & exposure assessment are interdependent*

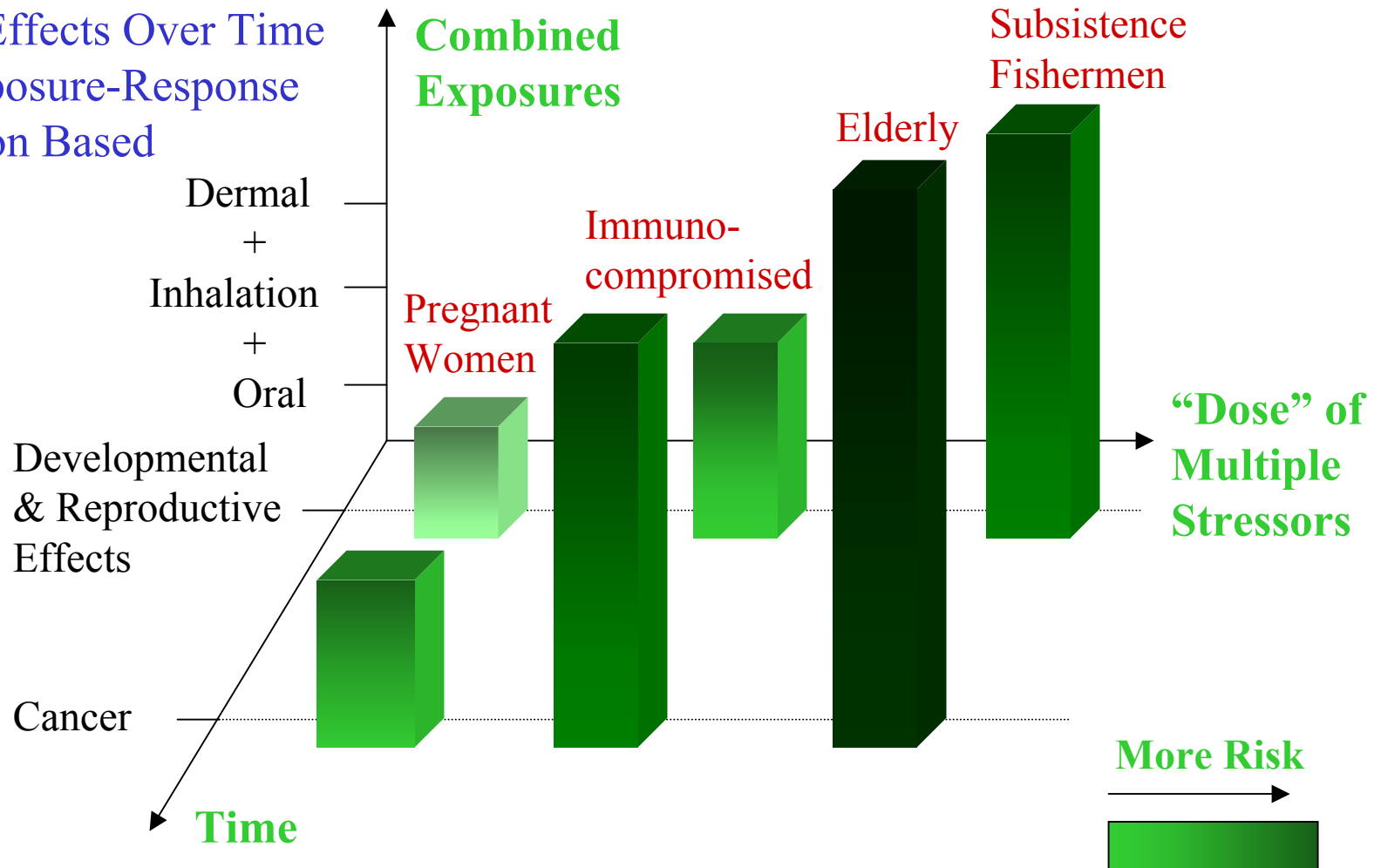
## *Risk characterization:*

- evaluate data support for assumptions about interactions, exposure, and similar toxicity of mixtures or their components.



# Cumulative Risk Characterization

- Several Stressors
- Multiple Exposure Routes
- Several Effects Over Time
- Joint Exposure-Response
- Population Based



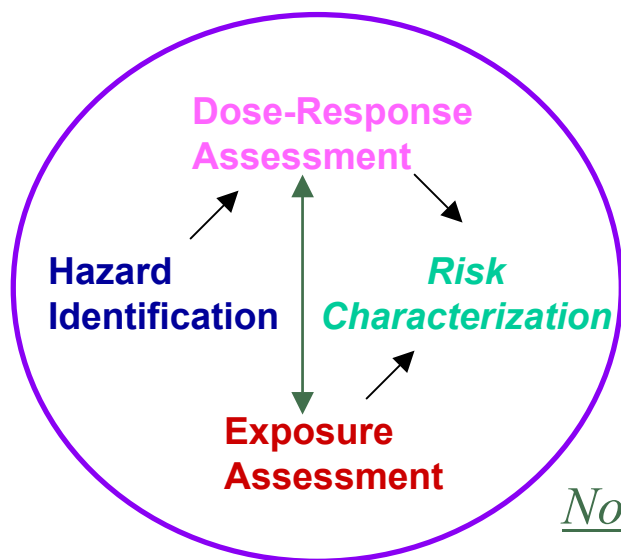
# Risk Assessment Paradigm for Cumulative Risk: In Addition to Issues for Chemical Mixtures

## *Hazard identification:*

- potential for multiple effects from multiple route exposures
- identify endpoints associated with non-chemical stressors

## *Exposure assessment:*

- account for multiple route exposures, including fate and transport for several media
- Identify cultural impacts on potential exposures



## *Dose-response:*

- account for total absorbed dose across exposure routes over time
- assess dose-response for an identified population

*Note: Dose-response & exposure assessment are interdependent*

## *Risk characterization:*

- use metrics accounting for disparate risks, detail uncertainties associated with combining risks, discuss qualitative factors affecting risk outcomes

# Research Needs Guided by Risk Assessment/Risk Management

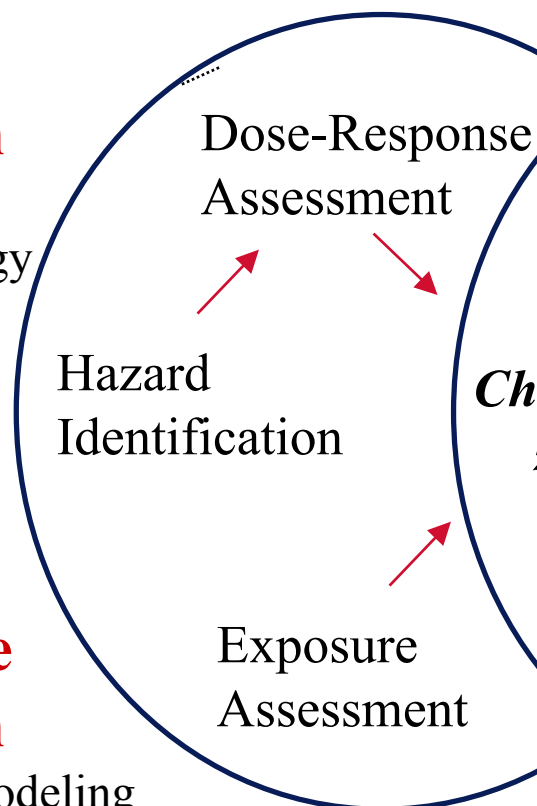
## Health Effects Research

- toxicology
- epidemiology
- cellular response
- genomics
- biomarkers

## Exposure Research

- exposure modeling
- monitoring technology
- analytical methods
- pharmacokinetic models

## Risk Assessment



## Risk Management

Control Options

Decision Making

Non-risk Analyses

## Risk Management Research

- engineering
- monitoring
- new technology

## Decision Sciences Research

- economics
- decision theory
- sociology
- public health
- comparative risks

## Risk Assessment Research

- methods development
- toxicity assessments
- statistics
- QSAR

## **Breakout Groups Basic Scope**

**Each group will have a facilitator and a recorder.**

**Basic activities for each group are to:**

- clarify that everyone understands the topic
- discuss what was heard during the day relevant to the topic area,
- identify needed improvements in current practices, data gaps, or deficiencies in available methods,
- prioritize those research needs (multi-voting is a quick method for this)
- report out to the larger workshop group

# **Breakout Groups**

## **Day 2 - Planning, Scoping and Community Issues**

### **Breakout Group 2-1 Problem Formulation**

**(Linda Teuschler, Roseanne Lorenzana)**

Bounding the analysis, developing hypotheses about possible cause and effect relationships, inventorying data sources, recognizing who should be involved

### **Breakout Group 2-2 Stakeholder Involvement (George Bollweg, Dave Klauder)**

Communication, communicating cumulative risk to the public, defining fundamental principles, educating the public

### **Breakout Group 2-3 Cumulative Risk Conceptual Models**

**(Ed Bender, Rick Hertzberg)**

Specifying data/technical requirements, what's needed to improve the process

### **Breakout Group 2-4 Community Issues (Eletha Brady-Roberts, Audrey Galizia)**

Environmental justice, special considerations for planning for sensitive or highly-exposed subpopulations

# **Breakout Groups**

## **Day 3 – Approaches to Cumulative Risk**

### **Breakout Group 3-1 Toxicology of Mixtures**

**(Rick Hertzberg, George Bollweg)**

Understanding toxicity of combinations of chemicals and how this impacts our ability to conduct a cumulative risk assessment

### **Breakout Group 3-2 Risk Assessment Approaches**

**(Mike Callahan, Linda Teuschler)**

What methods work and don't work in assessing cumulative risk

### **Breakout Group 3-3 Biomarkers (Jane Gallagher, Audrey Galizia)**

Using biomarkers in cumulative risk, technical challenges

### **Breakout Group 3-4 Cultural Impacts**

**(Eletha Brady-Roberts, Roseanne Lorenzana)**

Cultural factors that affect exposure assessment and identification of end points in cumulative risk assessments

# **Breakout Groups**

## **Day 4 – Approaches to Cumulative Risk**

### **Breakout Group 4-1 Risk Characterization Methods**

**(Rick Hertzberg, Jane Gallagher)**

Population based vs. source based risk assessments; identifying and accounting for uncertainty in cumulative risk, integrating risk information from multiple disciplines

### **Breakout Group 4-2 Combining Risks (Jim Cogliano, Jeff Yurk)**

Ways to express cumulative risks, disparate risks, choice of metric, ranking systems

### **Breakout Group 4-3 Ecology, Human Health and Tribal Approaches**

**(Linda Teuschler, Dave Klauder)**

Differences and similarities in approaches to cumulative risk in these areas

### **Breakout Group 4-4 Vulnerability (Mike Callahan, Ed Bender)**

Data gaps and methodologic difficulties in conducting a vulnerability analysis, capturing vulnerability factors in the risk characterization, such as climate variability, socioeconomic welfare, placement of waste facilities, cultural practices